STATEMENT OF SENATOR ARLEN SPECTER

THE STEM CELL RESEARCH ADVANCEMENT ACT

(As prepared for delivery)

Mr. SPECTER. Mr. President, I have sought recognition today to introduce the "Stem Cell Research Advancement Act" to codify the provisions set out in President Obama's executive order on embryonic stem cell research.

I believe medical research should be pursued with all possible haste to cure the diseases and maladies affecting Americans. As former Chairman and Ranking Member of the Labor, Health and Human Services, and Education Appropriations Subcommittee, I backed up this belief by supporting increases in funding for the National Institutes of Health. When I came to the Senate in 1981, NIH spending totaled $3.6 billion. In fiscal year 2010, NIH will receive approximately $31 billion to fund its pursuit of lifesaving research. Regrettably, increases in Federal funding for NIH have steadily declined since 2003. The $10 billion for the National Institutes of Health that was included in the stimulus package provided an immediate infusion of new research dollars for medical research to make up for a portion of what was lost since 2003 and has had tremendous influence on the biomedical research community. The successes realized by this investment in NIH have spawned revolutionary advances in our knowledge and treatment for diseases such as cancer, Alzheimer's disease, Parkinson's disease, mental illnesses, diabetes, osteoporosis, heart disease, ALS, and many others. For example, in the 1950's, cardiovascular disease caused half of U.S. deaths. Today, the death rate for coronary heart disease is more than 60 percent lower. Over the past 25 years, the 5-year survival rate for prostate cancer has

increased from 69 percent to almost 99 percent for diagnosed patients. For all childhood cancers combined, 5-year relative survival has improved markedly over the past 30 years, from less than 50 percent before the 1970s to 80 percent today. It is clear to me that Congress's commitment to the NIH is paying off. This is the time to seize the scientific opportunities that lie before us and to ensure that all avenues of research toward cures – including stem cell research – remain open for investigation.

I first learned of the potential of human embryonic stem cells in November of 1998 upon the announcement of the work by Dr. Jamie Thomson at the University of Wisconsin and Dr. John Gearhart at Johns Hopkins University. I took an immediate interest and held the first congressional hearing on the subject of stem cells less than one month later on December 2, 1998. These cells are pluripotent, meaning they have the ability to become any type of cell in the human body. The consequences of this unique property of stem cells are far reaching and are key to their potential use in therapies. Scientists and doctors with whom I have spoken – and that have since testified before the Labor-HHS Appropriations Subcommittee at 20 stem cell-related hearings – were excited by this discovery. They believed that these cells could be used to replace damaged or malfunctioning cells in patients with a wide range of diseases. This could lead to cures and treatments for maladies such as juvenile diabetes, Parkinson's disease, Alzheimer's disease, cardiovascular diseases, and spinal cord injury.

Embryonic stem cells are derived from embryos that would otherwise have been discarded. During the course of in vitro fertilization therapies, 4 to 16 embryos are created for a couple having difficulty becoming pregnant. The embryos grow for 5 to 7 days until they contain

approximately 100 cells. To maximize the chances of success, several embryos are implanted into the woman. The remaining embryos are frozen for future use. If the woman becomes pregnant after the first implantation, and does not want to have more pregnancies, the remaining frozen embryos are in excess of clinical need and can be donated for research. Embryonic stem cells are derived from these embryos. The stem cells form what are called "lines" and continue to divide indefinitely in a laboratory dish. The stem cells contained in these lines can then be made into almost any type of cell in the body--with the potential to replace cells damaged by disease or accident. At no point in the derivation process are the embryos or the derived cells implanted in a woman, which would be required for them to develop further. The process of deriving stem cell lines results in the disruption of the embryo and I know that this raises some concerns.

More than 400,000 embryos are stored in fertility clinics around the country. If these frozen embryos were going to be used for in vitro fertilization, I would be the first to support it. In fact, I have included funding in the HHS budget each year since 2002 to create and continue an embryo adoption awareness campaign. For fiscal year 2010, this campaign is funded at $4.2 million. But the truth is that most of these embryos will be discarded, while they hold the key to curing and treating diseases that cause suffering for millions of people.

President Bush opened the door to stem cell research on August 9, 2001. His policy statement allowed limited Federal funding of human embryonic stem cell research for the first time. A key statement by the President related to the existence of approximately 60 eligible stem cell lines – then expanded to 78. In the intervening years, it became apparent that many of the

lines cited were not really viable, robust, or available to federally funded researchers. During that time, there were only 21 lines available for research.

On July 18, 2006, the Senate passed H.R. 810, the Stem Cell Research Enhancement Act by a vote of 63 to 37. This was the House companion to S. 471, which I introduced, and would lift the federal date restriction and allow federally-funded scientists to research a greater number of stem cell lines derived from human embryos that have been donated from in vitro fertilization clinics. It also included stronger ethical requirements on stem cell lines eligible for funding including: donor consent, certification that embryos donated are in excess of clinical need, and certification that the embryos would be otherwise discarded. Unfortunately, on July 19, 2006, President Bush vetoed H.R. 810 and the House failed to override the veto by a vote of 235-93, 48 votes short of the two-thirds needed.

On March 19, 2007, Dr. Elias Zerhouni, President Bush's appointee to lead the National Institutes of Health, testified before the Senate Labor, Health and Human Services and Education Appropriations Subcommittee regarding the NIH budget and stem cells. At that time he stated, "It is clear today that American science would be better served and the nation would be better served if we let our scientists have access to more cell lines…To sideline NIH in such an issue of importance, in my view, is shortsighted. I think it wouldn't serve the nation well in the long run."

On March 9, 2009, President Obama issued an executive order removing restrictions on federal research on human embryonic research. On July 7, 2009, NIH issued the National Institutes of Health Guidelines for Research Using Human Stem Cells specifying the

requirements that must be met for an embryonic stem cell line to be eligible for use in NIH-funded research. Embryonic stem cell lines must be derived from donated human embryos created using in vitro fertilization for reproductive purposes, but no longer needed for that purpose, and donated with voluntary informed consent. This action and research advancement resulted in 75 stem cell lines available for NIH research.

Regrettably, on August 23, 2010, Chief Judge Lamberth of the Federal District Court for the District of Columbia ruled that such research violates the Dickey-Wicker amendment. Since fiscal year 1996, the Dickey-Wicker amendment has been added to each year's Labor, Health and Human Services and Education appropriations legislation to prohibit the use of federal funds for research that destroys human embryo. This policy precludes the use of federal funding to derive stem cells from embryos, which typically are produced via in vitro fertilization. However, it has always been interpreted as allowing federal funds for research that utilizes human embryonic stem cells as long as no federal funds were used for their derivation.

According to a legal opinion issued by the HHS General Council Harriet Rabb in 1999, federal funding for research performed with embryonic stem cells themselves, which does not itself involve embryos or the extraction of stem cells from embryos, is not proscribed by the Dickey amendment. The opinion states: “Pluripotent stem cells are not organisms and do not have the capacity to develop into an organism that could perform all the life functions of a human being. They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin producing cells. Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus. Based on an analysis of

the relevant law and scientific facts, federally funded research that utilizes human pluripotent stem cells would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such stem cells are not human embryos."

In their memorandum in support of dismissing the case before Judge Lamberth, the Department of Justice argued that "Congress has expressly interpreted Dickey-Wicker to permit federal funding for stem cell research that is 'dependent upon' the destruction of human embryos." As part of this argument, they cited a floor statement I gave in 1999, in regard to the NIH's fiscal year 2000 budget. In that statement, I explained that the budget for NIH maintained the Dickey-Wicker amendment by permitting research to go forward now with private funding extracting the stem cells from embryos, and then the federal funding coming in on the stem cells which have been extracted.

Judge Lamberth's ruling has jeopardized NIH grants that are in various stages of research. In response to this court order, the NIH suspended funding new human embryonic stem cell research and all experiments already underway will be cut off when they come up for renewal. Even a temporary suspension of funding will disrupt the work on these important research projects in the areas of heart disease, sickle cell anemia, liver failure, muscular dystrophy and other maladies. According to the National Institutes of Health, to date, $546 million has been spent on human embryonic stem cell research and phenomenal progress has already been made in realizing the possible benefits. For example, the Food and Drug Administration has approved a clinical trial for patients with spinal cord injury and human embryonic stem cell research is successfully being used to develop new therapeutic drugs for a number of diseases, including

amyotrophic lateral sclerosis and spinal muscular atrophy. The research, some of which has been ongoing since 2002, could be gone forever or take years to recreate.

Though the U.S. Court of Appeals for the D.C. Circuit has granted a stay of Judge Lamberth's temporary injunction while the Obama administration appeals the decision, the uncertainty created by the ruling slows the progress of science. Young scientists rightly void fields of science for which funding may come and go due to political whim rather than scientific and medical merit. A temporary end to the current restrictions is an incomplete and ultimately self-defeating solution.

The Stem Cell Research Advancement Act would codify federal funding of embryonic stem cell research. The bill requires the Secretary of HHS and Director of NIH to maintain guidelines on human stem cell research as set out by President Obama's Executive Order. The NIH must review the guidelines at least every three years and shall update them as scientifically warranted. The bill also establishes eligibility criteria for federal funding of human stem cell research:

- The stem cells were derived from human embryos donated from in vitro fertilization clinics, were created for reproductive purposes, and are in excess of clinical need.
- The embryos to be donated would never be implanted in a woman and would otherwise be discarded.
- The individuals seeking reproductive treatment donated the embryos with written informed consent and without any financial or other inducements.

Importantly, the bill does not allow Federal funds to be used for the derivation of stem cell lines – the step in the process where the embryo is destroyed.

I strongly believe that the funding provided by Congress should be invested in the best research to address diseases based on medical need and scientific opportunity. Politics has no place in the equation. I urge this body to support the Stem Cell Research Advancement Act so that scientists can continue important research without concerns that federal policy on stem cells will change with each new administration.